

DETAILED ACTION

Election/Restrictions

1. Applicant's species election without traverse in the reply filed on March 16, 2011 is acknowledged. The species election of diamine oxidase as a protein, a cation exchanger, a 0.1 M Tris succinate buffer pH 6.5 adsorption buffer, a 0.1 M Tris succinate buffer, pH 6.5 wash buffer, and a 0.1 M Tris succinate, pH 8.0 elution buffer is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant's state claims 1-7, 9, 10, and 13 read on the chosen species.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 8, 11, and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species and/or inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 16, 2011.
3. Claims 1-7, 9, 10, and 13 are currently under examination as drawn to the elected species.

Priority

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The priority date is March 30, 2004.

Information Disclosure Statement

5. The information disclosure statements (IDSs) submitted on October 19, 2006 and April 25, 2007 are being considered by the examiner. The signed 1449 forms are attached with the

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instant office action. The references on the 10/19/2006 IDS are crossed-out because they are not in English and no translations have been provided.

As the elected species in the particular combination as elected were not found in the prior art, a second species was examined for search purposes.

Claim Rejections - 35 USC § 102/ Claim Rejections - 35 USC § 103

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-7, 9, 10, and 13 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tsonev et al. (US 2007/0144973 A1).

Tsonev et al. disclose the method for the separation of charged molecules such as proteins according to the isoelectric points (pI's) and includes the systems and buffering compositions employed for isolating charged molecules. The invention further provides for modifications to the above described chromatographic methods that enable the separation of charged molecules exhibiting virtually identical pI's by shifting both the buffer's pKa and the pI's of the eluted charged molecules while they are traversing the ion exchange column. Tsonev et al. disclose the state of the art of isolation of proteins using a pH gradient and isoelectric focusing. The use of Tris-succinate as the buffer does not appear to offer any unexpected results for purification of proteins. It was known in the art that buffers in the mobile phase affect the charge of ion exchange resins and the ionic state of the substance to be purified (i.e. proteins). Absent any evidence of unexpected results for the particular buffering system used, the invention is prima facie obvious to the person having ordinary skill in the art.

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In addition, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); >see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.");< ** *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Conclusion

11. No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND DESAI whose telephone number is (571)272-0947.

The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571)272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

May 23, 2011

/ANAND U DESAI/

Primary Examiner, Art Unit 1656